Building the Foundation for Healing

The CAMPs Readiness Algorithm for Risk Stratification, Wound Bed Preparation, and Treatment Decision-Making

Supported by an educational grant from Organogenesis Inc.

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Faculty Disclosures

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- **Paula Pons, MD, CWSP**
  Consultant, Speakers Bureau: Organogenesis Inc.

Disclosures

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Learning Objectives

- Apply evidence-based assessment strategies to accurately diagnose chronic wounds, including vascular evaluation, nutritional assessment, prognostic indicators, and diagnostic imaging to guide treatment planning and risk stratification
- Implement foundational wound bed preparation principles by incorporating appropriate debridement, biofilm management, and moisture balance strategies to optimize healing potential and prepare patients for advanced therapies, including CAMPs
- Evaluate treatment effectiveness and clinical decision-making through the use of wound measurement, including 4-week area-reduction benchmarks and case-based application of established guidelines to improve patient outcomes

CAMPs = cellular, acellular, and matrix-like products.

Optimizing Healing Potential through Evidence-Based Assessment, Diagnosis, and Wound Bed Preparation

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Background

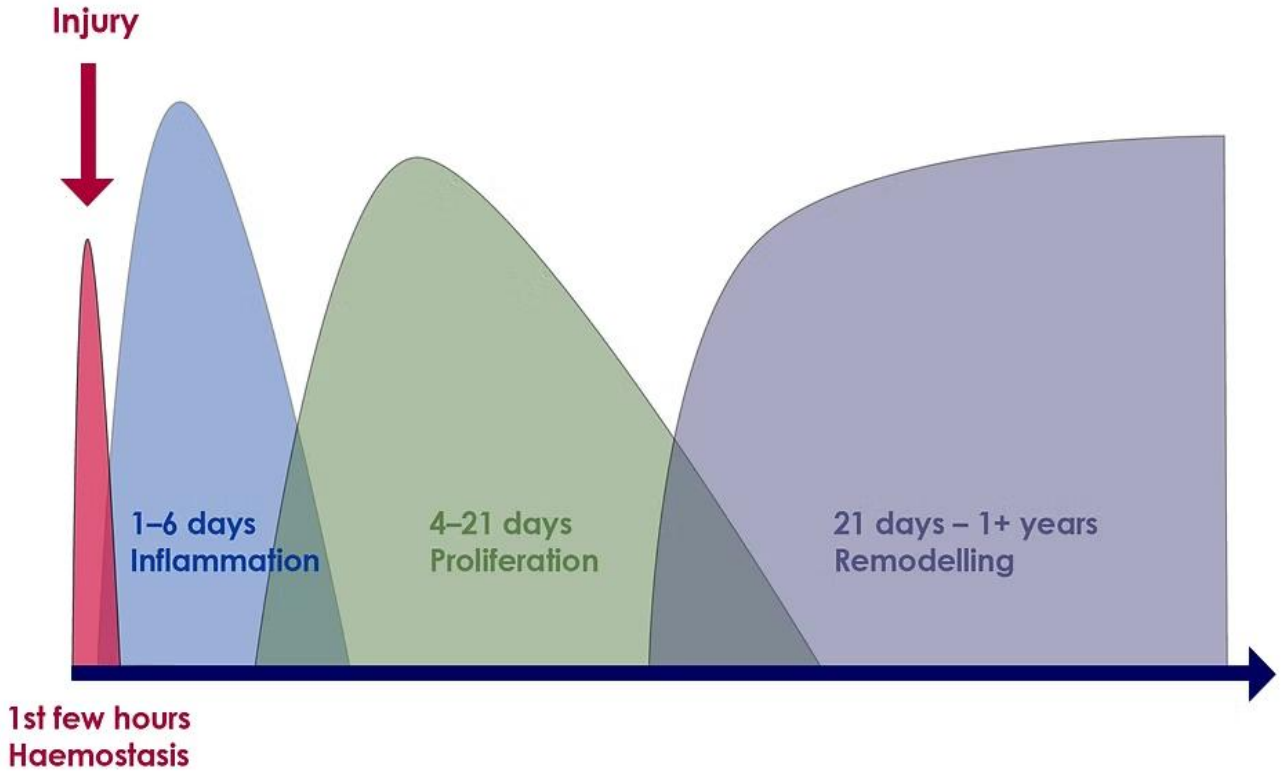
Chronic wounds fail to progress through the normal, orderly, and timely stages of healing, failing to restore tissue integrity

- Public health concern
- 10.5 million people in the U.S. live with chronic wounds
- Annual $200 billion impact on the healthcare system
- Additionally, patients suffer from
  - Loss of productivity
  - Psychological distress
  - Decreased quality of life
  - Reduced life expectancy



Bowers S, Franco E. *Am Fam Physician*. 2020;101(3):159-166. Sen CK. *Adv Wound Care (New Rochelle)*. 2025;14(9):429-438.

Stalling



Inflammation

- Excessive bacterial bioburden and biofilm
- Pro-inflammatory macrophages (M1)
- Increased neutrophil accumulation
- Pro-inflammatory cytokines
- Elevated matrix metalloproteinase (MMP) levels
- Decreased tissue inhibitor of metalloproteinase (TIMP levels)

Proliferation

Cells

- Impaired keratinocytes and fibroblasts
- Impaired migration and proliferation
- Decreased response to signaling molecules

Signaling molecules

- Growth factors and cytokines at abnormal levels

Matrix

- Impaired ECM production and maintenance

MMP = matrix metalloprotease; TIMP = tissue inhibitor of metalloproteinase; ECM = extracellular matrix.

Stadelmann WK, et al. *Am J Surg*. 1998;176(2A Suppl):26S-38S.

Diagnosis and Assessment

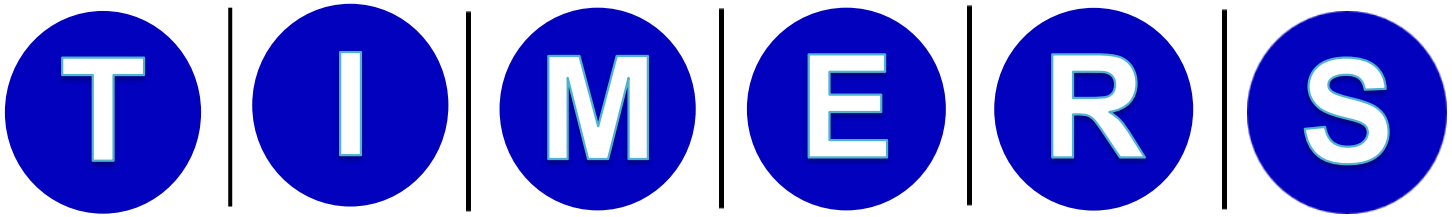
Accurate diagnosis of chronic wounds requires multimodal assessment with the goal to correctly identify the wound etiology, stratify risk, and guide targeted treatment

Patient history	• Wound history, comorbidities, surgical history, medications, social determinants, etc.
Vascular	• Clinical assessment (wound aspect, pallor, dependent rubor, edema, pulses, etc.) • Ankle-brachial index and toe pressures • Near-infrared spectroscopy • Transcutaneous oxygen measurement • Arterial duplex • Angiogram • Venous doppler and reflux study
Nutrition	• Anthropometric measures (weight trends, BMI, and muscle mass indicators) • Dietary intake analysis (caloric, protein, vitamin intake) • Serum markers (albumin, prealbumin, and C-reactive protein (CRP)
Imaging	• Digital wound imaging systems (for consistent measurement and monitoring) • Fluorescence imaging (detects bacterial burden) • X-ray (bone erosion, fractures, foreign bodies) • MRI/CT (osteomyelitis, deep tissue infection)
Tissue cultures	• Cultures • Biopsy

→ Etiology

De Francesco F, Riccio M. (2026). Clinical Assessment of Hard-to-Heal Wounds: Tools, Evidence, and Multidisciplinary Strategies. In: De Francesco F, Turksen K. (eds) Management and Strategies for Wound Healing. Stem Cell Biology and Regenerative Medicine, vol 79. Springer, Cham.

Standard of Care



Tissue	Debridement removes nonviable tissue, helps manage bioburden and infection, and aids in the maintenance of moisture balance
Infection / Inflammation	Reduction of inflammation and infection by means of debridement, use of topical antimicrobials and systemic antibiotics
Moisture Control	Adequate use of dressings, gels, NPWT, etc.
Edge of Wound	Awareness of epithelial edge advancement aiming for 40% wound area reduction after 4 wks of treatment
Regeneration	Utilization of advanced therapies (CAMPs, HBOT, autologous skin graft, etc.)
Social Factors	Social situation, patient understanding and education, psychosocial factors, patient's own goals, caregiver education, etc.

NPWT = negative pressure wound therapy; HBOT = hyperbaric oxygen therapy.

Atkin L, et al. *J Wound Care*. 2019;23(Suppl 3a):S1-S50.

Standard of Care

Pressure Relief

- Surfaces
- TCC
- Boots
- Shoes







Compression

- Compression wraps
- Lymphedema wraps
- Compression pumps



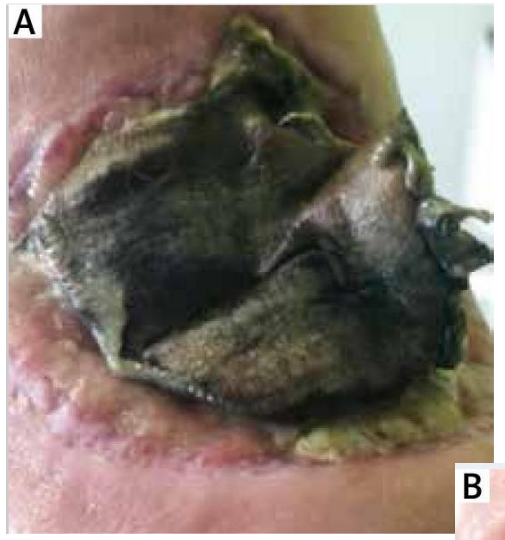



TCC = total contact casting.

Lavery LA, et al. *Int Wound J.* 2015;12(6):710-715. O'Meara S, et al. *Cochrane Database Syst Rev.* 2012;11(11):CD000265.

Wound Bed Preparation

- Debridement
- Biofilm management
- Moisture balance strategies
- Optimize endogenous healing potential
- Prepare wounds for advanced therapies





Nowak M, et al. *Postepy Dermatol Alergol*. 2022;39(3):479-490.

Debridement

Removal of nonviable or contaminated tissue that impedes normal tissue growth while eliminating biofilm, infection, and senescent cells







Effective and frequent debridement improves healing rates

Cardinal M, et al. *Wound Repair Regen*. 2009;17(3):306-311. Falanga V, et al. *Ostomy Wound Manage*. 2008 Jun;Suppl:2-13; quiz 14-5. Nowak M, et al. *Postepy Dermatol Alergol*. 2022;39(3):479-490.

Debridement

Should be performed even in the face of a seemingly healthy wound bed if the wound is not showing evidence of closure

- Improves microcirculation in the wound
- Reduces inflammation
- Lowers of level of metalloproteinases
- Stimulates wound edge epithelization
- Reduces bacterial load and manages biofilm
- Reduces risk of infection
- Improves patient quality of life

Falanga V, et al. *Ostomy Wound Manage*. 2008 Jun;Suppl:2-13; quiz 14-5.

Effective Debridement

- Thorough cleansing of wound and skin
- Topical anesthesia
- Excision of nonviable and viable tissue
- Removal of any debris, dressing, foreign material
- Removal of infected or nonviable bone
- Removal of callus
- Saucerize edges as needed
- Management of biofilm/bioburden
- Obtain samples for culture and pathology as needed
- Obtain hemostasis
- Rinse wound
- Apply dressing conducive to moisture control
- Follow up with repeat debridement if wound is not improving



Falanga V, et al. *Ostomy Wound Manage*. 2008 Jun;Suppl:2-13; quiz 14-5.

Clinical Pearls

- Accurate, evidence-based assessment and diagnosis
- Management of comorbidities
- Tailored treatment strategy
- Effective and frequent debridement
- Management of bioburden
- Treatment of infection
- Maintenance of moisture balance
- Pressure relief/compression
- Wound bed preparation to optimize healing potential can prepare for advanced therapies, including CAMPs

TREAT THE WHOLE PATIENT **AND** THE HOLE ON THE PATIENT

Advanced Care: When and Why

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The Clinical Problem

Diabetic Foot Ulcers (DFUs)



Venous Leg Ulcers (VLUs)



DFU = diabetic foot ulcer; VLU = venous leg ulcer.

Common Chronic Wounds

High Prevalence

High Cost

High Complications

Burden of Disease

Journal of Medical Economics 2014, 1–10
1369-6998
doi:10.3111/13696998.2014.903258
Article 0156.R1/903258
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Original article
Burden of venous leg ulcers in the United States

Table 5. Estimated annual incidence of VLU in Medicare and private insurance.

	Medicare			Private insurance		
Year	New patients[a]	Total patients[b]	Incidence[c]	New patients[a]	Total patients[b]	Incidence[c]
2007	23,644	1,116,983	2.1%	8322	1,917,988	0.4%
2008	23,348	1,094,325	2.1%	7556	1,545,801	0.5%
2009	24,369	1,089,946	2.2%	7592	1,507,734	0.5%
2010	–	–	–	10,009	1,656,530	0.6%
Total	71,361	3,301,254	2.2%	33,479	6,628,053	0.5%

[a]New patients defined as those with at least one VLU diagnosis in the calendar year but no VLU diagnosis in the previous year. Patients were also required to meet other sample selection criteria (in terms of age restrictions and enrollment).
[b]Total patients were defined as those with at least one medical claim and continuous non-HMO insurance coverage in the year of estimation as well as the previous year.
[c]Incidence was calculated by dividing the number of new patients by the number of total patients in the calendar year.





Venous Leg Ulcers:
Prevalence = 2.2 million patients annually in the U.S.

Incremental costs of VLU: $6000- $7000

Increased work loss days: 4 per patient

Total incremental costs of VLU: $14.9 billion





Venous Leg Ulcers:
Prevalence = 2.2 million patients annually in the U.S.

Faster Healing of DFUs Is Critical

DFUs put patients at risk for serious complications, including osteomyelitis and amputation

85%

of leg amputations preceded by a DFU

15%

of DFUs result in lower extremity amputation



Every 5 minutes

a lower-limb amputation occurs*

Patients with DFUs or diabetes-related amputations have

5-yr mortality rates

Worse than many common types of cancers

*In patients with diabetes.

Giurato L, et al. *World J Diabetes*. 2017;8(4);135-142. Lipsky BA, et al. *Diabetes Metab Res Rev*. 2016;32(suppl 1):45-74. Singh N, et al. *JAMA*. 2005;293(2):217-228. Snyder RJ, Hanft JR. *Ostomy Wound Manage*. 2009;55(11):28-38. Centers for Disease Control and Prevention. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf. Accessed Dec 12, 2019. Armstrong DG, et al. *J Foot Ankle Res*. 2020;13(1):16.

When to Use Advanced Products

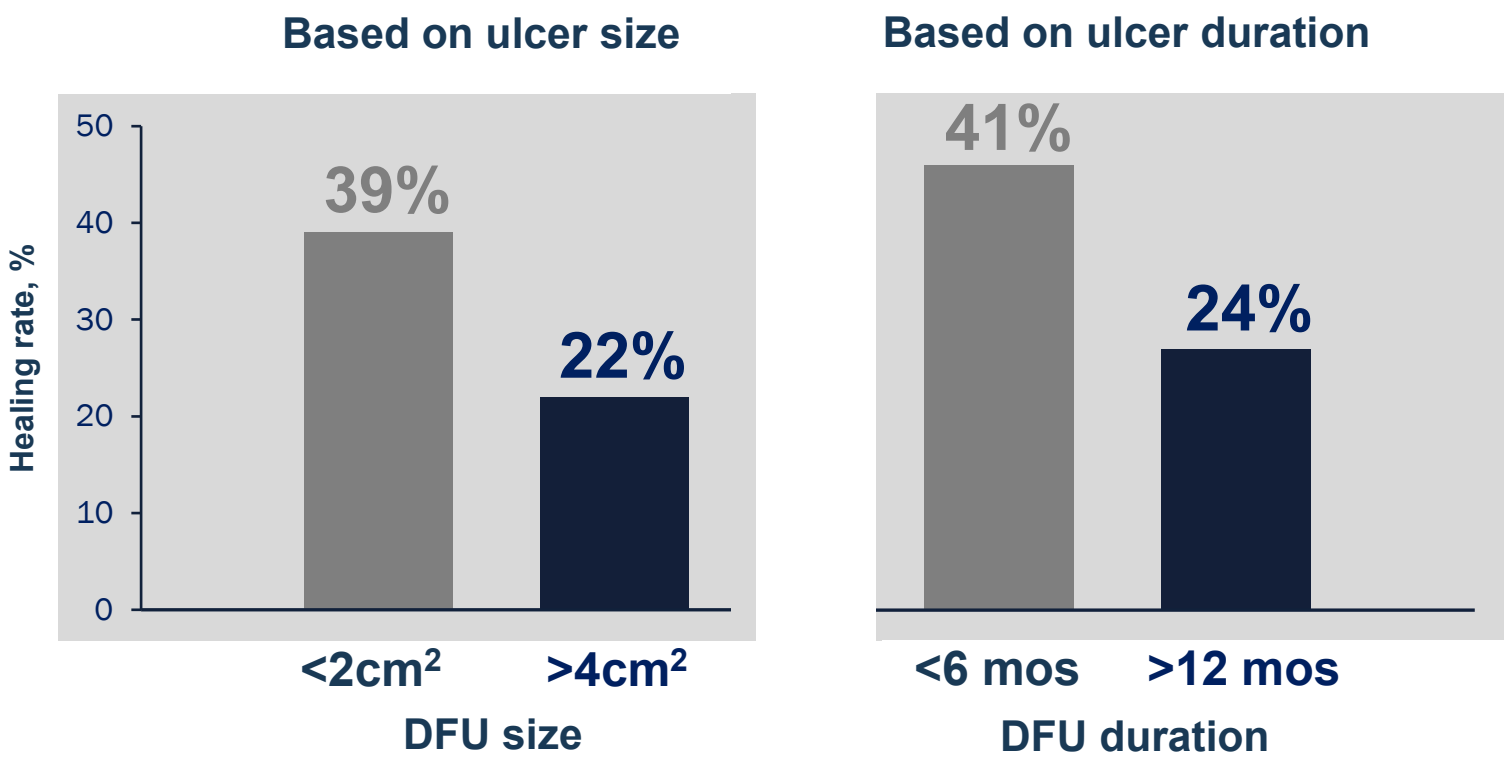
Ways to Predict Ulcer Healing

Baseline Predictors

Longitudinal Predictors

DFU Prognostic Indicators Highlight the Importance of Early Intervention

Healing rates at 20 wks



Increased baseline ulcer size and duration are associated with reduced rates of complete healing.

Margolis DJ, et al. *Diabetes Care*. 1999;22(5):692-695.

Risk Stratification Index For VLUs

A patient receives a score of "1" for each of the following criteria

- **Wound ≥ 5cm²**
- **Wound duration ≥ 6 months**

	Area	Duration (months)		Index Score
Wound #1	≥5cm²	≥6 months	Neither met	0
Wound #2	≥5cm² ⟷	≥6 months	Either met	1
Wound #3	≥5cm²	≥6 months	Both met	2

From the validation section of the study, N=219		
"0"	n=20	95% healed in 24 wks
"1"	n=79	73% healed in 24 wks
"2"	n=120	37% healed in 24 wks

Kantor J, Margolis DJ. *Br J Dermatol.* 2000;142(5):960-964.

Confirmation Study

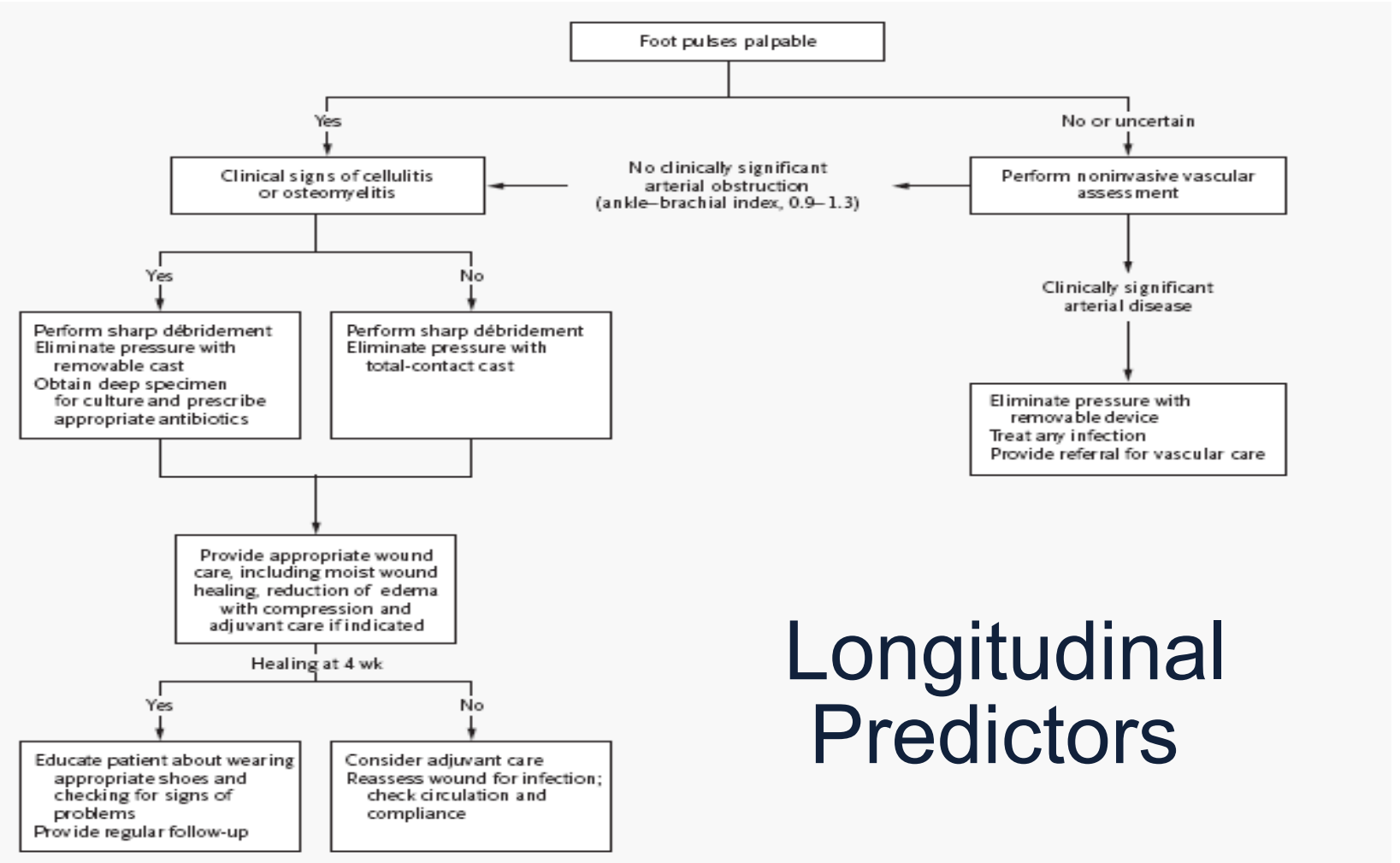
Proportion healed and time to complete healing by prognostic group

Proportion Healed, (%)	12-wk trials	24-wk trials	Total
Prognostic Index = 0	68.3%	89.8%	77.5%
Prognostic Index = 1	48.1%	60.1%	54.5%
Prognostic Index = 2	17.4%	22.8%	20.3%
Total	52.0%	62.9%	57.4%

Days to healing, median	12-wk trials	24-wk trials	Total
Prognostic Index = 0	35.0 days	48.0 days	40.0 days
Prognostic Index = 1	48.0 days	84.0 days	57.0 days
Prognostic Index = 2	56.0 days	111.5 days	86.5 days
Total	41.0 days	61.0 days	49.0 days

Jull A, et al. *J Wound Care*. 2023;32(10)



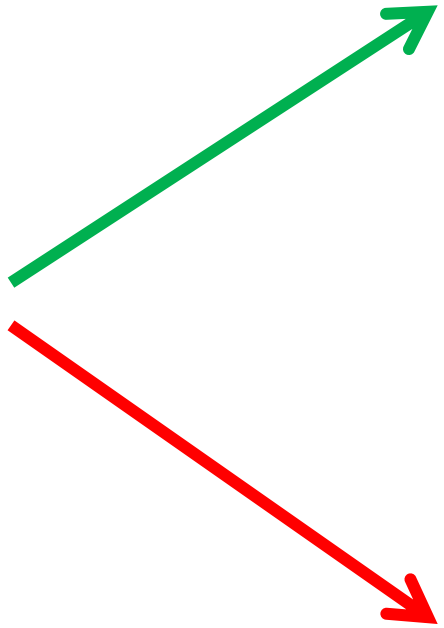


Longitudinal Predictors

Singer AJ, Tassiopoulos A, Kirsner RS. *NEJM*. 2017;377(16):1559-1567. Boulton AJM, Kirsner RS, Vileikyte L. *NEJM.* 2004;351:48-55.

Standard Care

Compression: VLU
Offloading: DFU



Improving:

Continue standard care

Not Improving:

Continue standard care
Add adjunctive care

Which Advanced Products to Use

What Makes Evidence Actionable?

CLINICAL RELEVANCE

- Demonstrates statistically and clinically meaningful improvements in wound closure
- Evaluates outcomes that directly impact patient care, including healing rates and time to closure

PATIENT APPLICABILITY

- Studies include patients and wound types commonly encountered in clinical practice
- Evidence supports product use as an adjunct to standard of care in appropriate, non-healing wounds

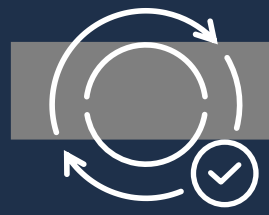
CONSISTENCY ACROSS STUDIES

- Positive outcomes demonstrated across multiple clinical trials and real-world analyses
- Findings are reproducible across different care settings and patient populations

TRANSLATING EVIDENCE TO PRACTICE

- Clearly defined patient selection criteria help identify appropriate candidates for treatment
- Practical treatment protocols and application techniques can be readily incorporated into existing wound care workflows

Efficacy and Effectiveness



EFFICACY

CAN it work?

CLINICAL **TRIAL** DATA



EFFECTIVENESS

DOES it work?

REAL-WORLD DATA

Diagnosis and Management of Diabetic Foot Complications



American Diabetes Association.

2018

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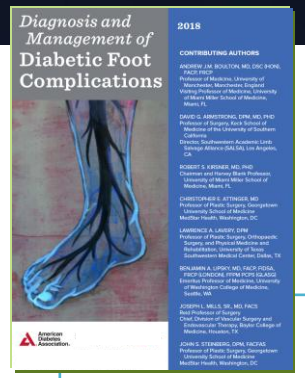
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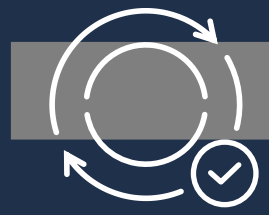
Evidence-Based Advanced Therapies

(1 indication and of >80+ products)

Wound Care	rhPDGF *n*=382	PRP *n*=35	HSE *n*=208	DSS *n*=245	IDRT *n*=307	SIS *n*=82	HADVM *n*=86	hVWM *n*=97	dHACM *n*=40	NPWT *n*=162	HBOT *n*=90
Healed, %	50 vs 35 at 20 wks	81 vs 42 at 12 wks	56 vs 38 at 12 wks	30 vs 18 at 12 wks	51 vs 31 at 16 wks	54 vs 32 at 12 wks	68 vs 46 at 12 wks	62 vs 21 at 12 wks	95 vs 35 at 6 wks	56 vs 39 at 16 wks	52 vs 29 at 1 yr
Time to closure, days	86 vs 127	43 vs 47	65 vs 90	Not stated	43 vs 78	63 vs 77	40 vs 48	42 vs 70	24 vs 57	N/A	N/A
FDA-approved	+		+	+	+						
Study quality	+++	+	+++	+++	+++	++	++	++	+	++	++
Additional RCTs	+	+	+	+						+	+
Effectiveness data	+	+	+	+							
	Growth Factors		**Cellular constructs**		**Acellular constructs (AC)**		**PM**	**AC**	**PM**	**Other**	

*Because of differences in study design and quality, caution is warranted regarding direct comparisons.
rhPDGF = recombinant human platelet-derived growth factor; PRP = platelet-rich plasma; HSE = human skin equivalent; DSS = dermal skin substitute; IDRT = Integra Dermal Regeneration Template; SIS = small intestinal submucosa; HADWM = human acellular dermal wound matrix; hVWM = human viable wound matrix; HACM = dehydrated human amnion/chorion membrane allograft; NPWT = negative pressure wound therapy; HBOT = hyperbaric oxygen therapy; AC = acellular constructs; PM = placental membrane.

Efficacy

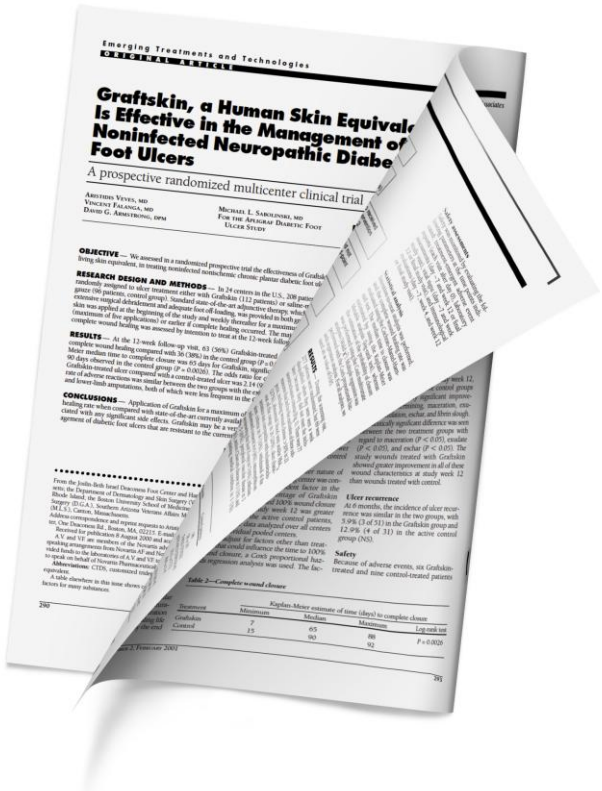


EFFICACY

CAN it work?

CLINICAL **TRIAL** DATA

BLCC DFU Randomized Controlled Trial (RCT) for FDA Approval



24 U.S. clinical sites

Baseline characteristics

	BLCC (n=112)	Control (n=96)
Age (yrs)	58 ± 10	56 ± 10
Male, %	78.5	77.1
BMI (kg/m^2)	30.9 ± 6.5	33.1 ± 7.7
Wound area (cm^2)	3.0 ± 3.1	2.83 ± 2.5
Wound duration (months)	**11.5 ± 13.3**	**11.1 ± 12.5**

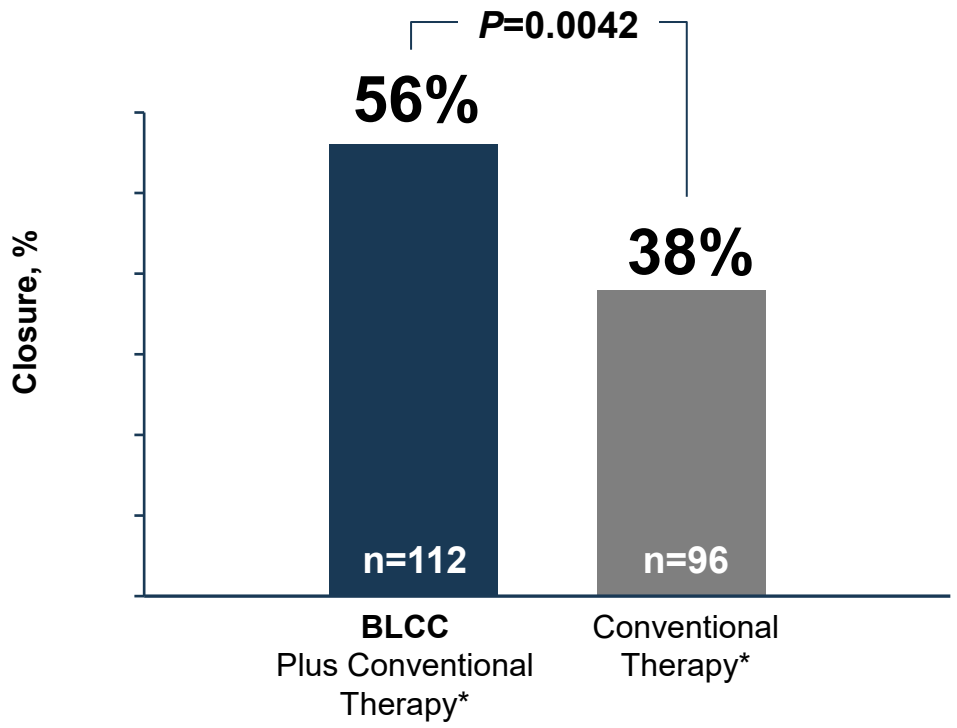
Wounds included were of long duration.

BLCC = bilayered living cellular construct.

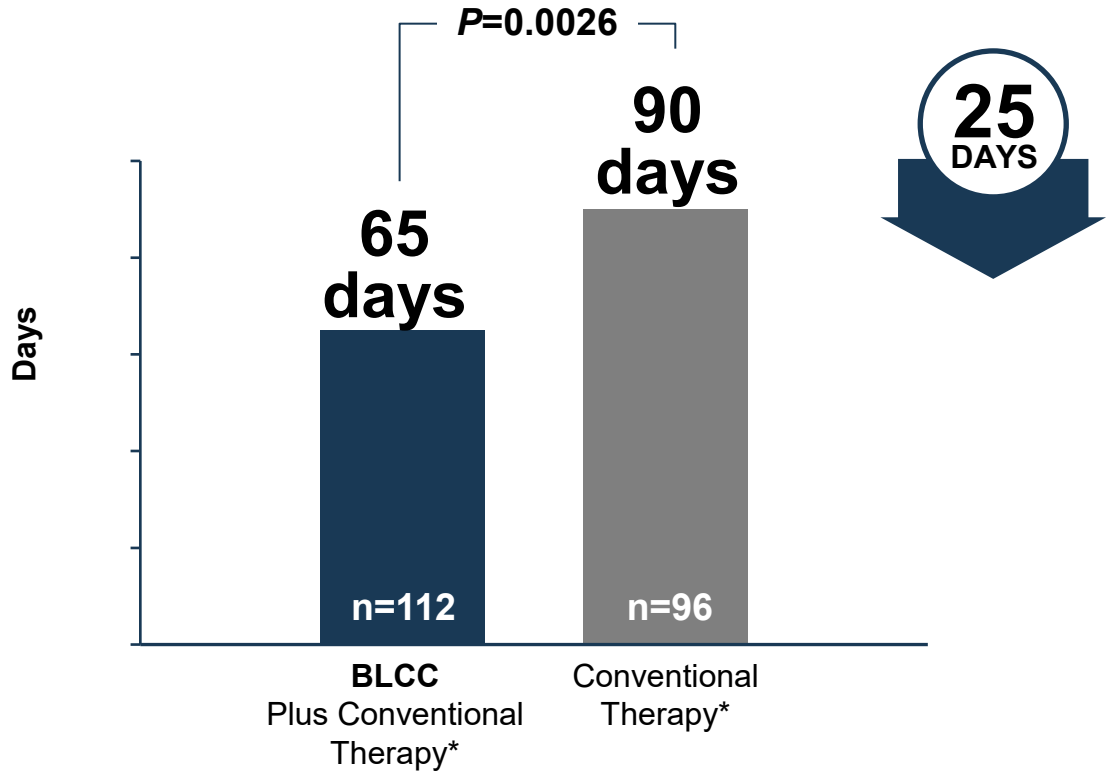
Veves A, et al. *Diabetes Care*. 2001;24(2):290-295.

In the DFU RCT, BLCC Healed More DFUs Faster

Incidence of Complete Wound Closure After 12 Wks[1]



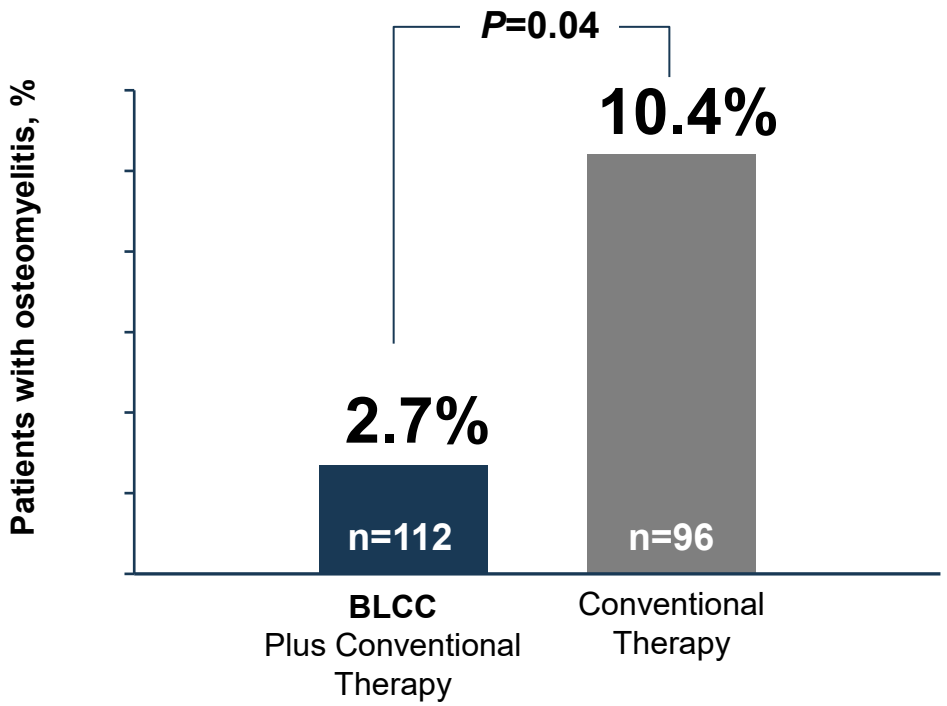
Median Time to 100% Wound Closure[1,a]



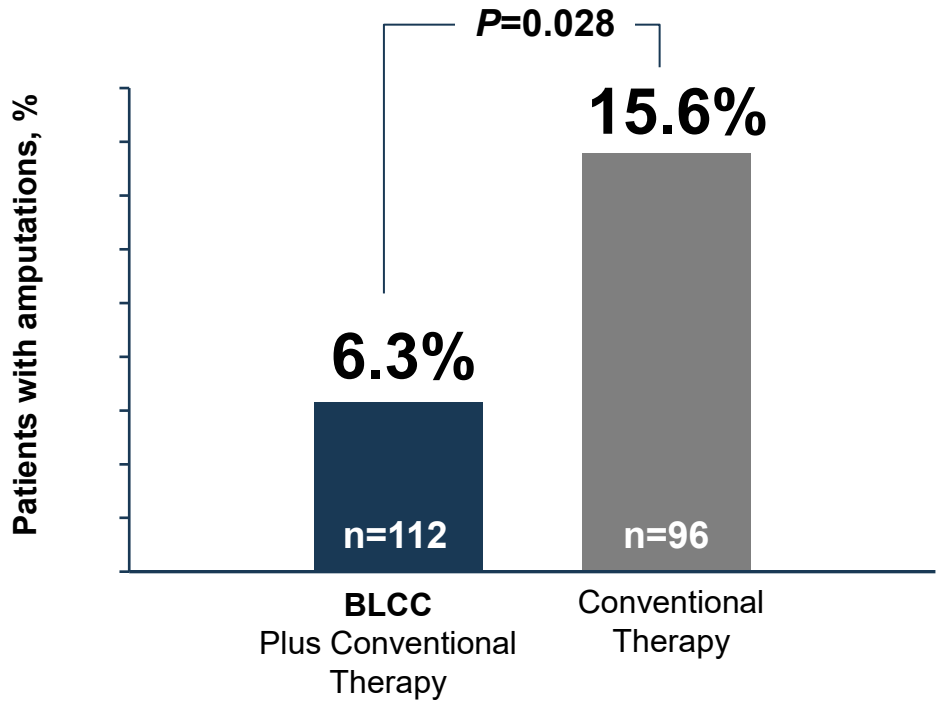
*Sharp debridement, use of saline-moistened dressings, and a non–weight-bearing regimen.
[a]Kaplan-Meier estimate of time (days) to complete closure.
1. Veves A, et al. Diabetes Care. 2001;24(2):290-295.

Lower Incidence of Osteomyelitis and Fewer Amputations in BLCC-Treated Patients

Incidence of Osteomyelitis (at the Study Site) after 6 Months[1]



Incidence of Amputations (on the Study Limb) after 6 Months[1]



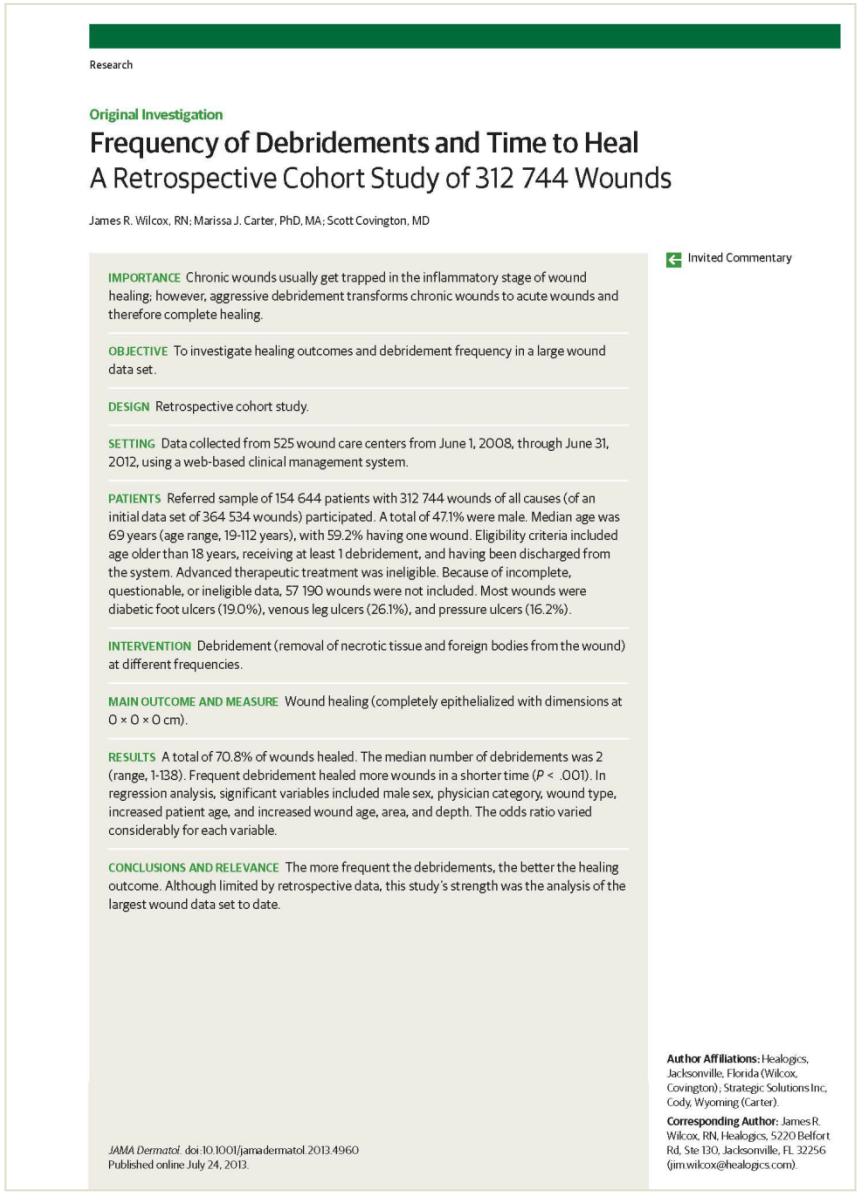
This study was not designed to determine the incidence of amputations or osteomyelitis. These data were acquired through evaluation of clinical trial adverse events.

1. Veves A, et al. *Diabetes Care*. 2001;24(2):290-295.

Effectiveness



EFFECTIVENESS DOES it work? REAL-WORLD DATA



Research

Original Investigation

Frequency of Debridements and Time to Heal
A Retrospective Cohort Study of 312 744 Wounds

James R. Wilcox, RN; Marissa J. Carter, PhD, MA; Scott Covington, MD

Invited Commentary

IMPORTANCE Chronic wounds usually get trapped in the inflammatory stage of wound healing; however, aggressive debridement transforms chronic wounds to acute wounds and therefore complete healing.

OBJECTIVE To investigate healing outcomes and debridement frequency in a large wound data set.

DESIGN Retrospective cohort study.

SETTING Data collected from 525 wound care centers from June 1, 2008, through June 31, 2012, using a web-based clinical management system.

PATIENTS Referred sample of 154 644 patients with 312 744 wounds of all causes (of an initial data set of 364 534 wounds) participated. A total of 47.1% were male. Median age was 69 years (age range, 19-112 years), with 59.2% having one wound. Eligibility criteria included age older than 18 years, receiving at least 1 debridement, and having been discharged from the system. Advanced therapeutic treatment was ineligible. Because of incomplete, questionable, or ineligible data, 57 190 wounds were not included. Most wounds were diabetic foot ulcers (19.0%), venous leg ulcers (26.1%), and pressure ulcers (16.2%).

INTERVENTION Debridement (removal of necrotic tissue and foreign bodies from the wound) at different frequencies.

MAIN OUTCOME AND MEASURE Wound healing (completely epithelialized with dimensions at 0 × 0 × 0 cm).

RESULTS A total of 70.8% of wounds healed. The median number of debridements was 2 (range, 1-138). Frequent debridement healed more wounds in a shorter time ($P < .001$). In regression analysis, significant variables included male sex, physician category, wound type, increased patient age, and increased wound age, area, and depth. The odds ratio varied considerably for each variable.

CONCLUSIONS AND RELEVANCE The more frequent the debridements, the better the healing outcome. Although limited by retrospective data, this study's strength was the analysis of the largest wound data set to date.

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JAMA Dermatol. doi:10.1001/jamadermatol.2013.4960
Published online July 24, 2013.

N=312,744 wounds

154,664 patients

525 wound care centers (WCCs)

4-yr period (2008-2012)

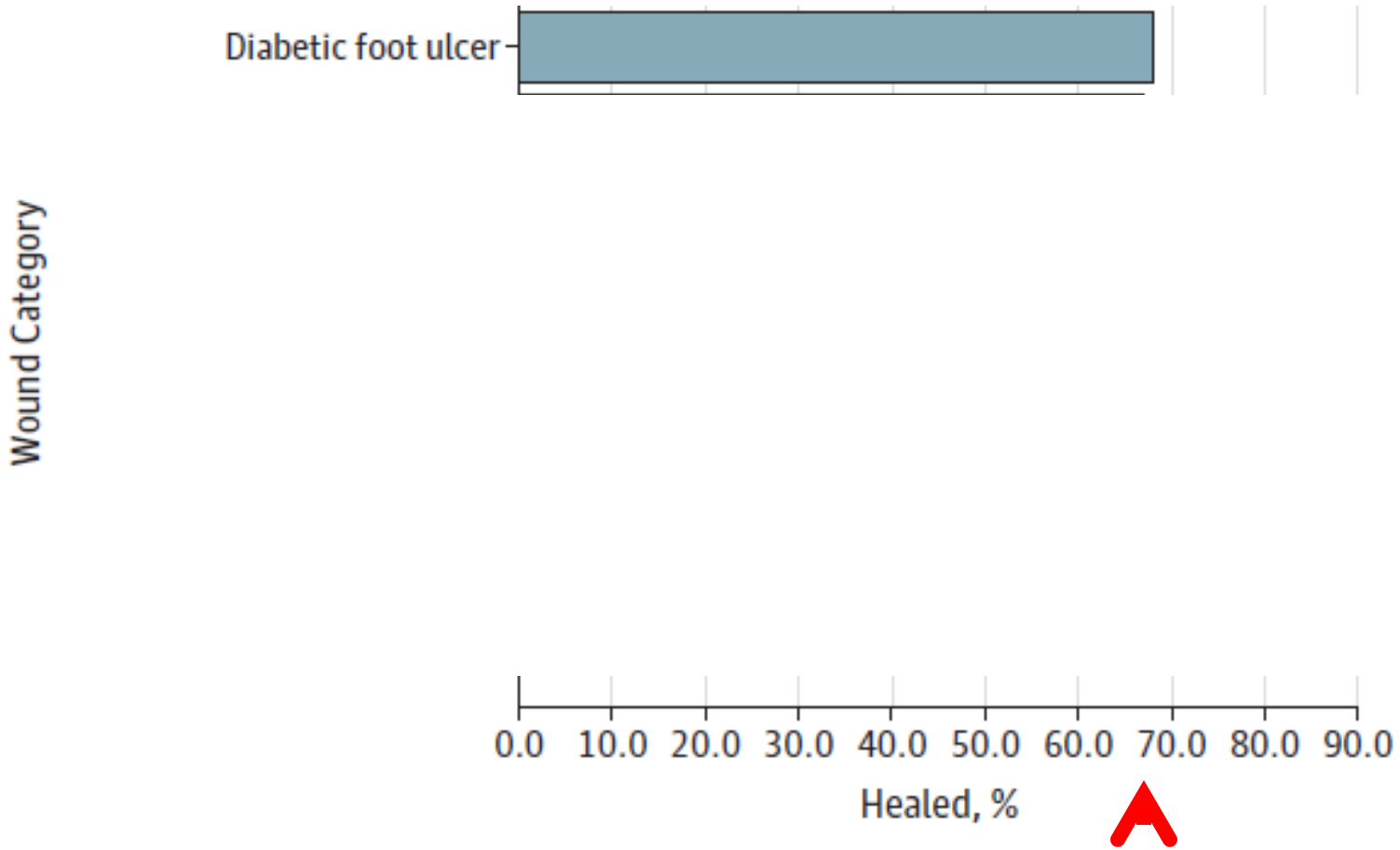
Most common wound types:

- VLU 26.1%
- DFU 19%
- PU 16.2%

Avg. # of debridements = 2 (range 1-138)

WCC = wound care center; PU = pressure ulcer.

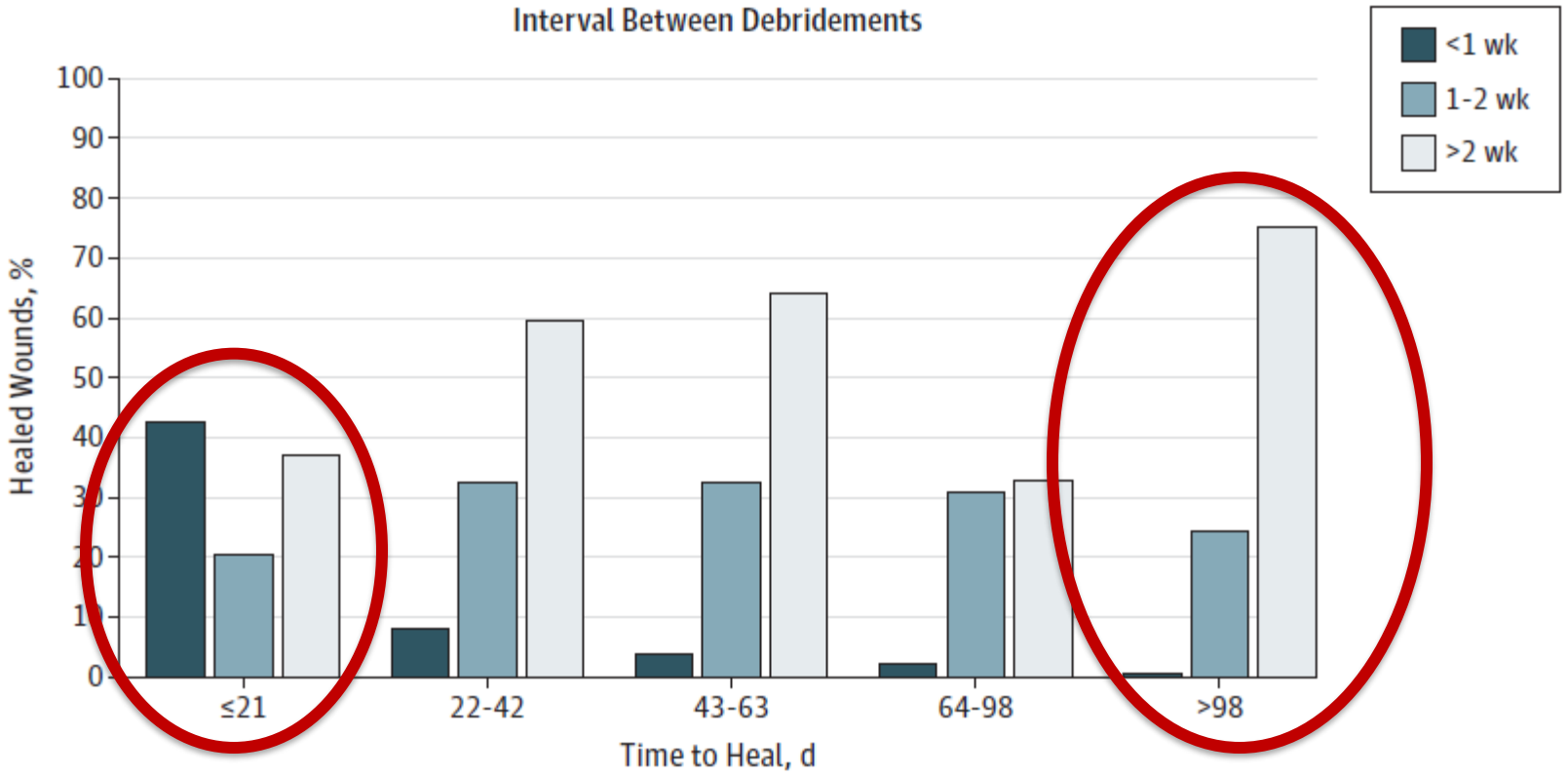
Wilcox J, et al. J*AMA Dermatol*. 2013;149(9):1050-1058.



Healing Rates for the Different Categories of Wounds

Wilcox J, et al. *JAMA Dermatol*. 2013;149(9):1050-1058.

Debridement Frequency vs Days to Heal: All Wound Types (321,744 Wounds)

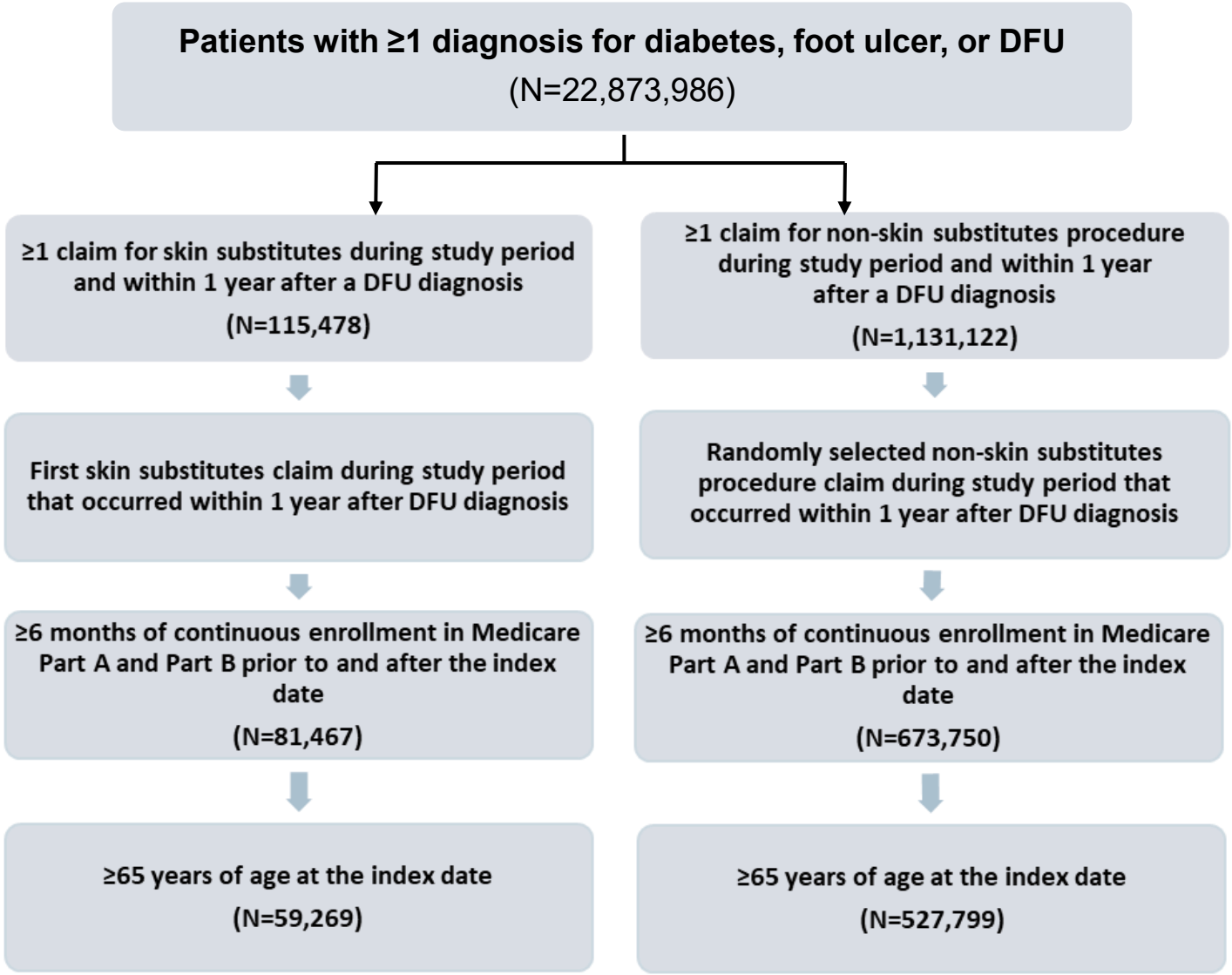


Wounds with debridement intervals of 1 wk or less healed significantly faster

Wilcox J, et al. *JAMA Dermatol*. 2013;149(9):1050-1058.

Methods: Sample Section

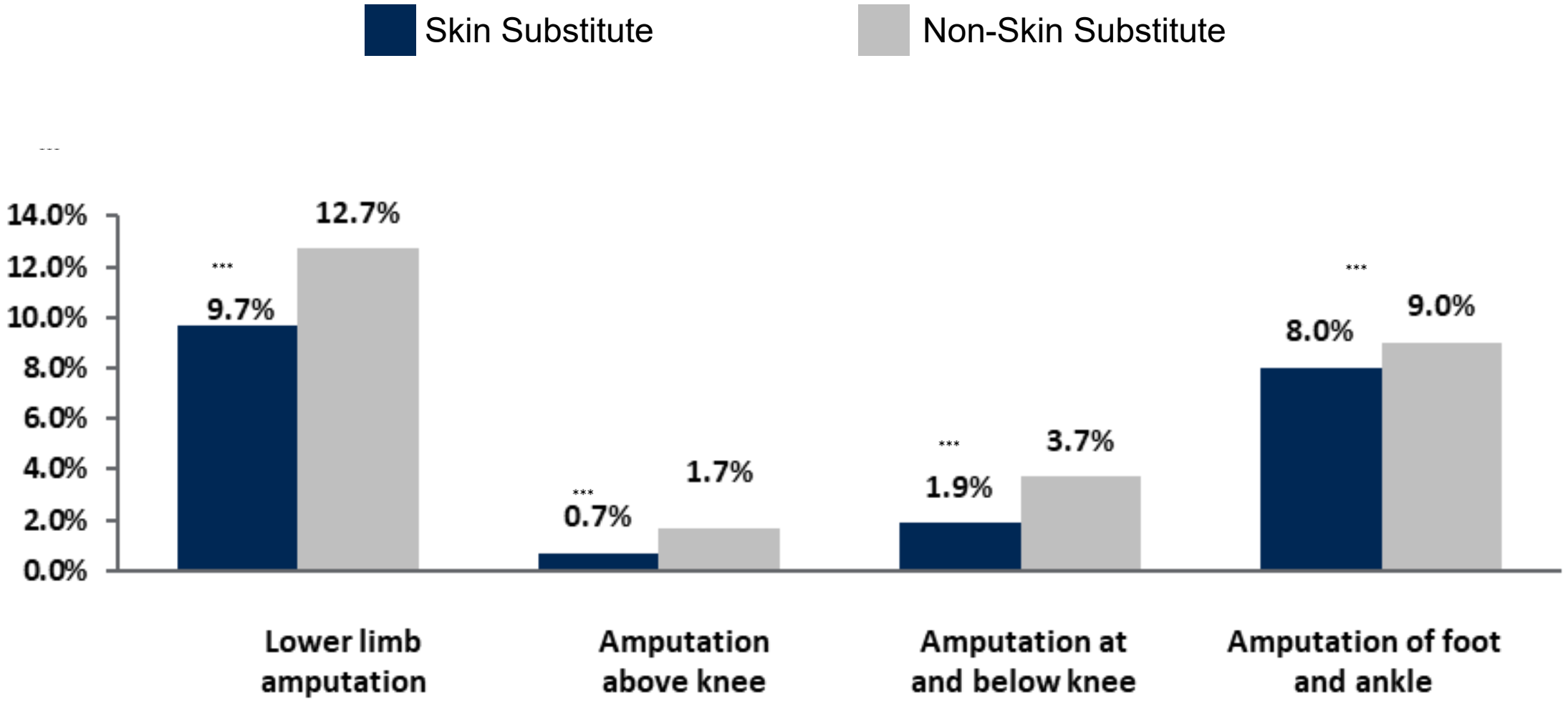
1. Identify all patients with relevant medical claims between January 1, 2015 and December 31, 2021
2. Identify skin substitutes and non-skin substitutes cohorts
3. Identify Index Date
4. Ensure complete visibility of Medicare coverage
5. Restrict to beneficiaries aged 65 and over



Results: Baseline Sample Characteristics

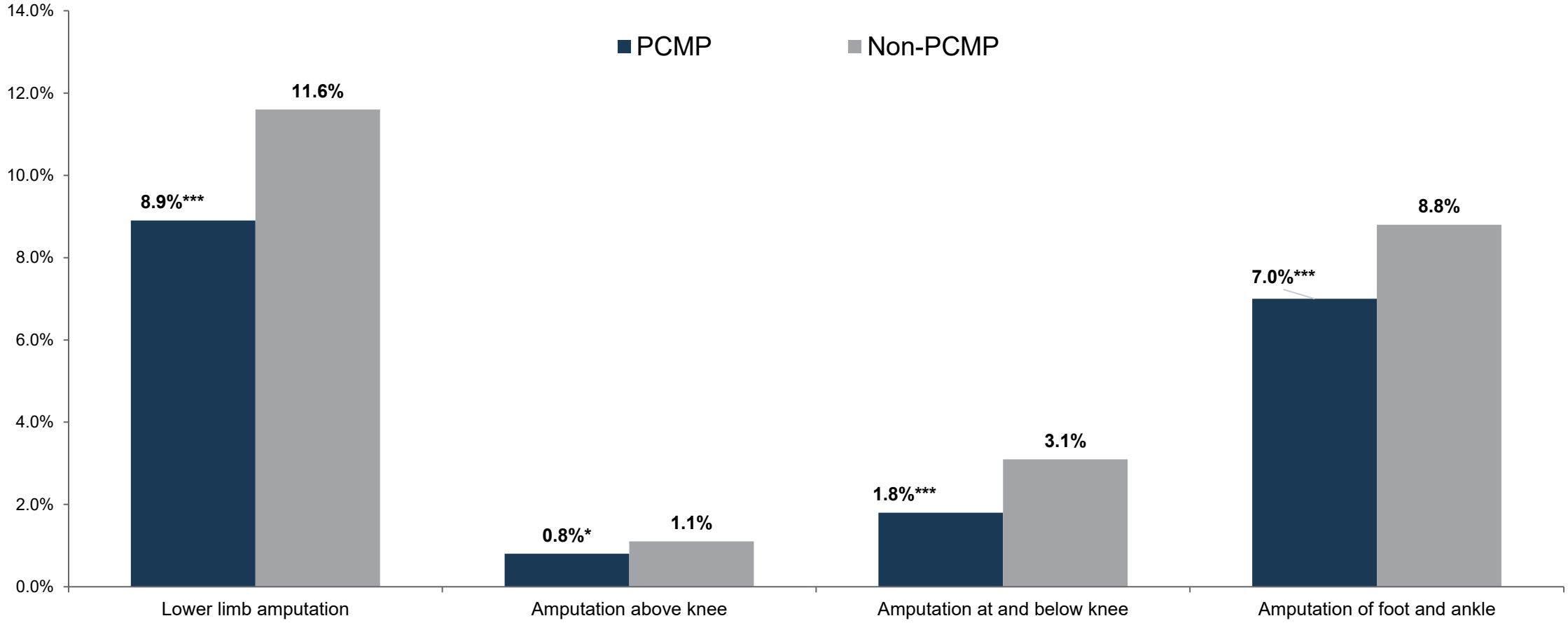
Selected characteristics	Pre-match			Post-match		
	Skin substitutes (N=59,269)	Non-skin substitutes (N=527,799)	P-value	Skin substitutes (N = 58,491)	Non-skin substitutes (N= 58,491)	P-value
Patient Demographics/Comorbidities						
Age, mean	75.9	77.5	<0.001	75.9	75.9	0.290
Male	62.0%	53.9%	<0.001	61.9%	62.7%	0.002
Charlson comorbidity index, mean	3.1	2.9	<0.001	3.1	3.2	<0.001
Select comorbid conditions, %						
Diabetes with complications	78.7%	66.2%	<0.001	78.5%	76.6%	<0.001
Peripheral vascular disease	69.8%	52.2%	<0.001	69.6%	63.5%	<0.001
Cerebrovascular disease	21.4%	22.0%	<0.001	21.3%	23.6%	<0.001
Congestive heart failure	39.7%	34.3%	<0.001	39.7%	39.0%	0.013
COPD	23.1%	21.8%	<0.001	23.1%	23.5%	0.114
Renal disease	46.5%	38.6%	<0.001	46.4%%	45.4%	0.001
Myocardial infarction	16.1%	12.2%	<0.001	16.1%	15.8%	0.185
Number of unique DFU diagnosis, mean	16.5	5.0	<0.001	15.8	14.4	<0.001
Severity						
Months of active ulceration	5.5	3.4	<0.001	5.5	5.9	<0.001
DFU related infections	68.2%	47.4%	<0.001	67.8%	69.7%	<0.001
Non-traumatic lower limb amputation	12.6%	6.4%	<0.001	12.4%	12.8%	0.037

Results: Reduction in Amputation Rates



P<0.001

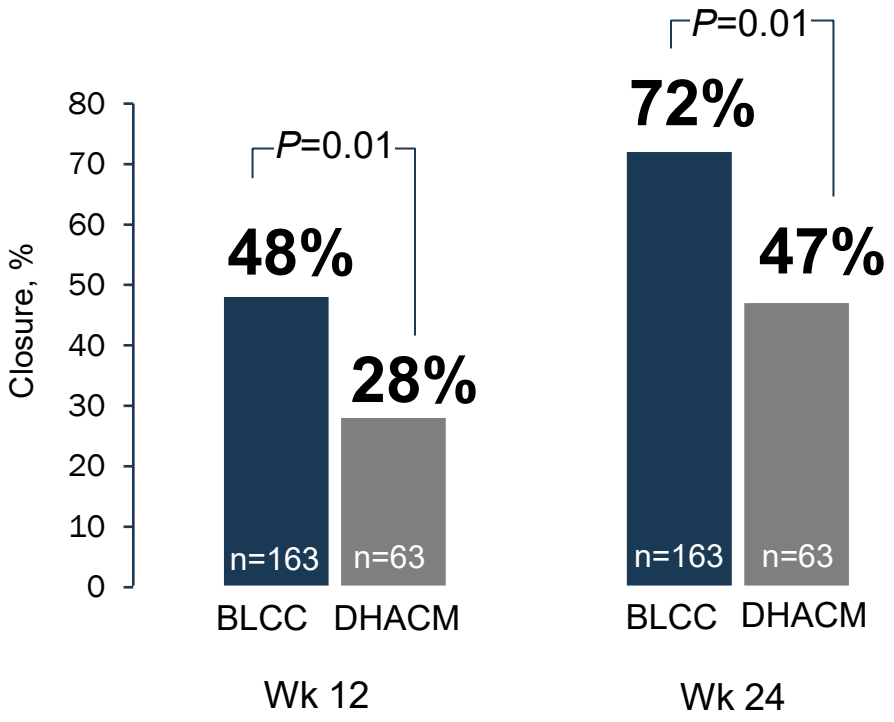
Non-traumatic lower-limb amputations during 6-month follow-up period after matching



Comparative Effectiveness

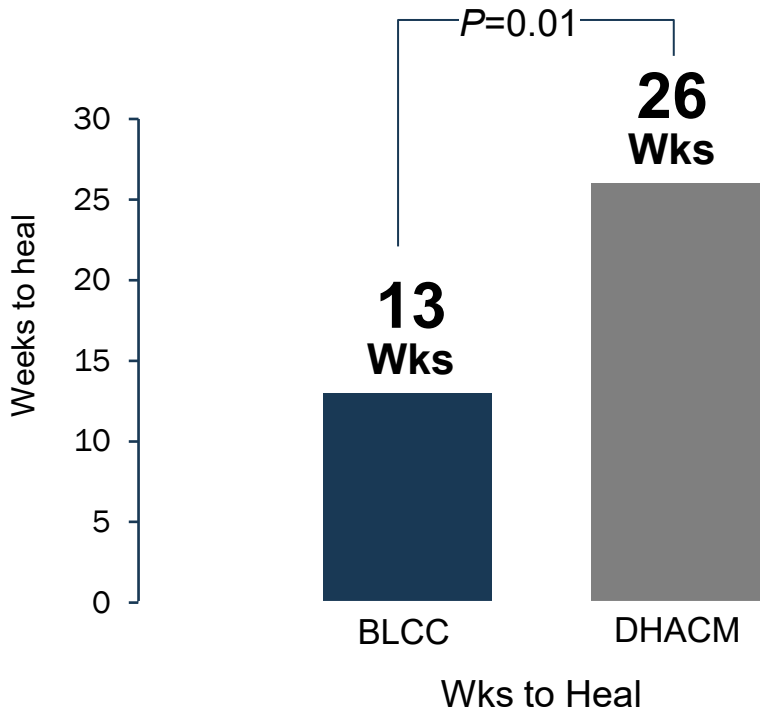
Real-World Observational Study Demonstrates That BLCC Heals More DFUs Faster

Frequency of DFU Closure[1]



Estimated frequency of wound closure and *P*-value are from a Cox regression model with terms for treatment, baseline wound area, duration, depth, and location. All 2014 data were included in the analysis.

Median Time to DFU Closure[1]



50% FASTER

Estimated wound closure and *P*-value are from a Cox regression model with terms for treatment, baseline wound area, duration, depth, and location. All 2014 data were included in the analysis.

Effectiveness is the extent to which an intervention produces an overall health benefit in routine clinical practice (real-world situations).
Effectiveness studies do not establish efficacy or comparative superiority.
EpiFix is a registered trademark of MiMedx Group, Inc.

1. Kirsner RS, et al. *Wound Repair Regen*. 2015;23(5):737-744.

Comparative Effectiveness

Advanced Products Appear to Be Reserved for More Challenging Wounds

STUDY

Advanced Biological Therapies for Diabetic Foot Ulcers

Robert S. Kirsner, MD, PhD; Robert Warriner, MD; Michelle Michela, MS; Laure Stasik, BA; Katherine Freeman, PhD

Objective: To assess the clinical use of advanced biological therapies in treating diabetic foot ulcers in practice and the effect of these therapies on time to healing.

Design: A retrospective cohort study.

Setting: A validated wound care database from January 1, 2001, through December 31, 2004.

Participants: Two thousand five hundred seventeen patients with diabetic neuropathic foot ulcers.

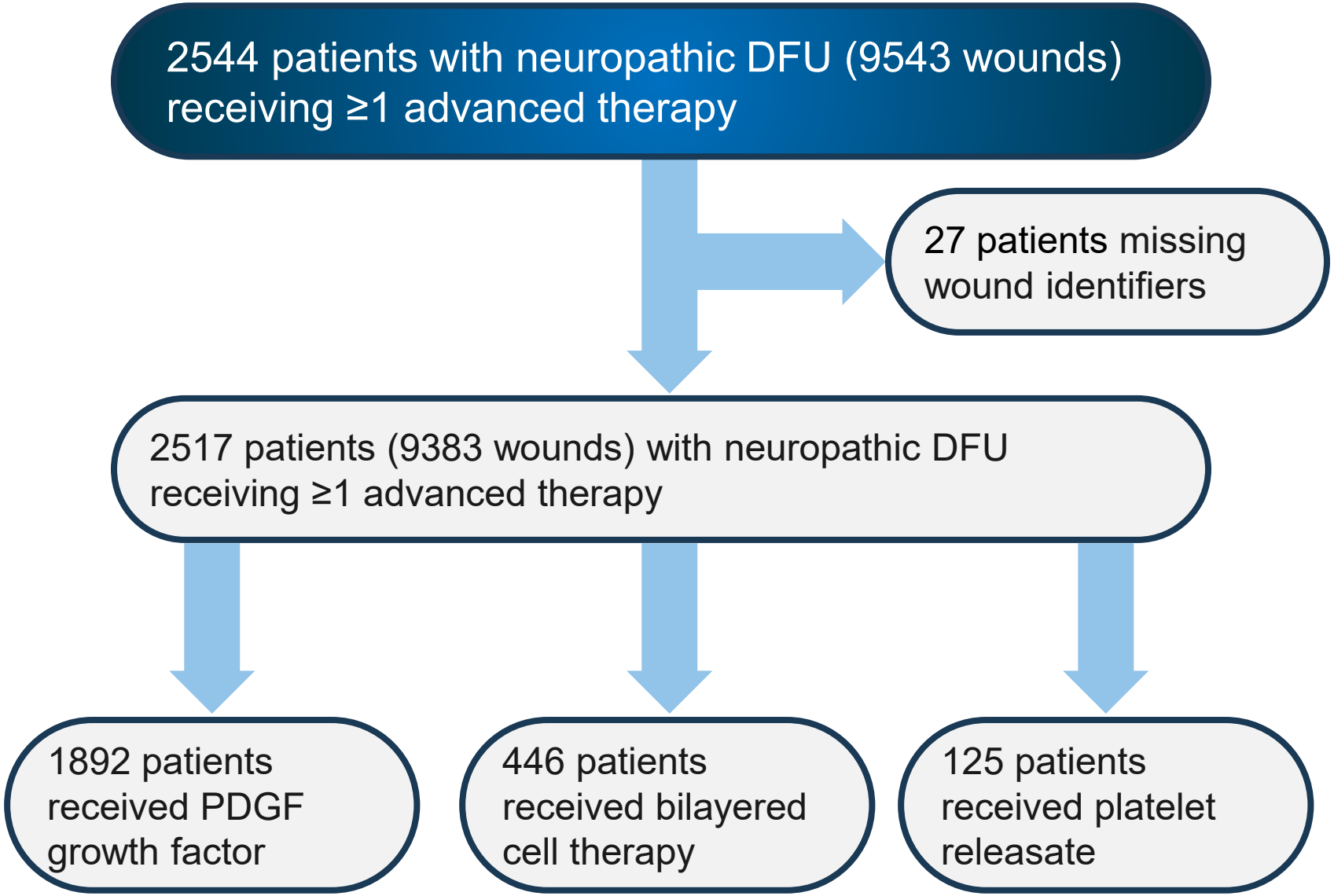
Intervention: Patients who received advanced biological therapy (ie, Apligraf, Regranex, or Procuren).

Main Outcome Measure: Time to healing after initial use of advanced biological therapy. This was derived using Kaplan-Meier estimates and the Ederer least squares method after adjusting for covariates, which were assessed using generalized estimating equations and Cox proportional hazards regression modeling.

Results: Advanced biological therapy was used, on average, within 28 days from the first wound clinic visit and associated with a median time to healing of 100 days. Regardless of the advanced biological therapy used, wounds with larger wound area, more severe wound grades, longer duration of wound prior to the first visit, and prolonged time to treatment with advanced biological therapies were significantly associated with longer time to healing. Wounds treated with engineered skin as the first advanced biological therapy were 31.2% more likely to heal than wounds first treated with topical recombinant growth factor ($P < .001$), and 40.0% more likely to heal than those first treated with platelet releasate ($P = .01$). Wound size, wound grade, duration of wound, and time to initiation of advanced biological therapy affected the time to healing.

Conclusions: Advanced biological therapies were used, on average, within 1 month, and improved healing of refractory diabetic foot ulcers. Differences on outcomes among advanced biological therapies were noted.

Arch Dermatol. 2010;146(8):857-862



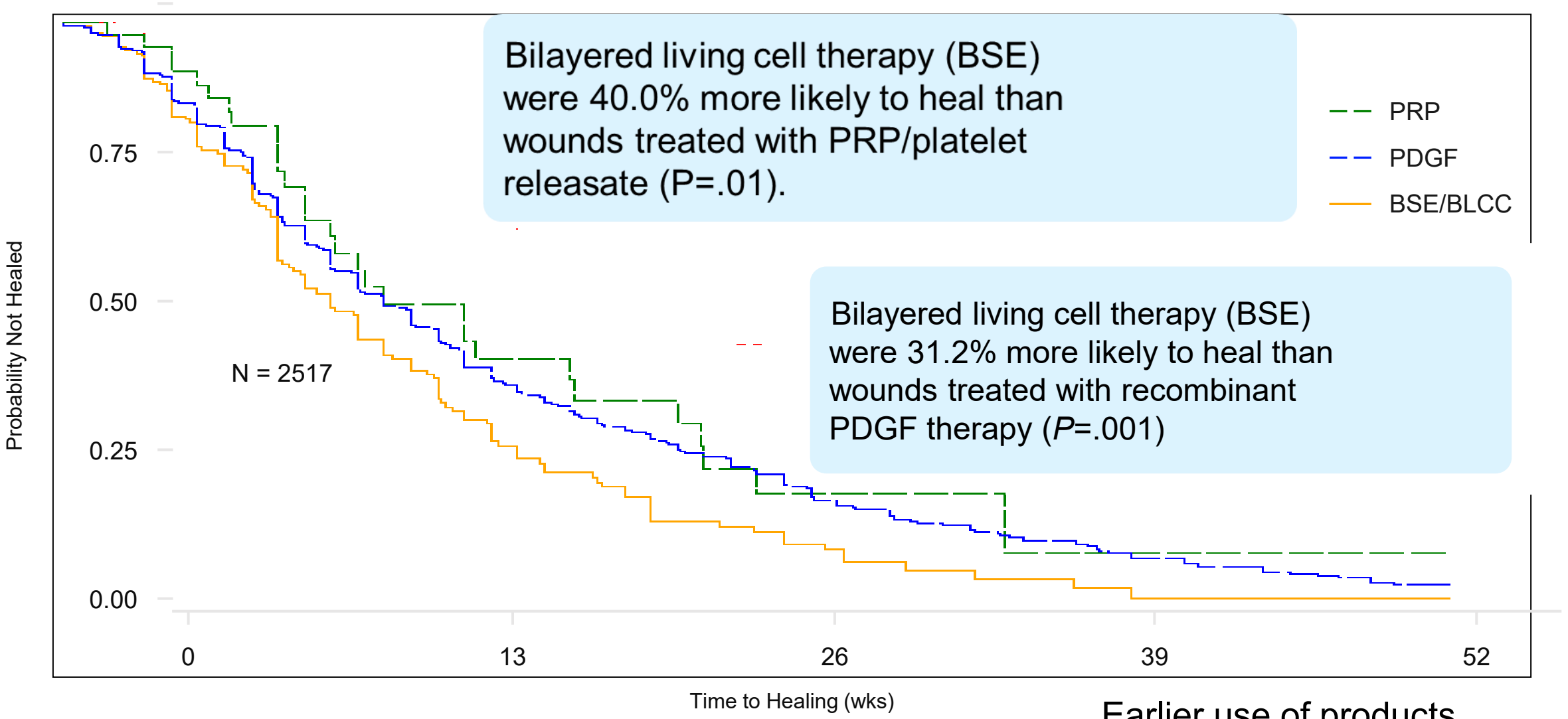
Kirsner R, et al. *Arch Dermatol.* 2010;146(8):857-862.

Baseline Characteristics of the Wound

Wound Characteristic	Analysis Population (n=2517)	Bilayered Living Cell Therapy[a] (n=446 [17.7%])	Becaplermin[a] (n=1892 [75.2%])	Platelet Releasate[a] (n=125 [5.0%])	*P* Value
Wound area, mm^2	117 (39-395)	311 (84-925)	141 (49-424)	329 (78-973)	< .001
Wound depth, mm	2 (1-5)	2 (1-5)	2 (1-5)	3 (2-10)	< .001
Duration prior to first visit, mo	1 (0.5-3)	2 (0.75-4)	1.5 (0.75-4)	1 (0.5-3)	.12
Time to advanced treatment use, d	28 (8-60)	43 (21-96)	23 (7-56)	28 (18-47)	< .001
Grade, No. (%)[b]					
0-1	75 (3.00)	12 (2.75)	59 (3.15)	3 (2.44)	
2	1879 (75.04)	345 (78.95)	1396 (74.45)	89 (72.36)	.25
>2	550 (21.96)	80 (18.31)	420 (22.40)	31 (25.20)	

Kirsner R, et al. *Arch Dermatol.* 2010;146(8):857-862.

Results



Earlier use of products resulted in better outcomes

Kirsner R, et al. *Arch Dermatol.* 2010;146(8):857-862.

Wound Repair Regen. 2020 Jul;28(4):547-552. doi: 10.1111/wrr.12818. Epub 2020 May 19.

A real-world experience with the bioactive human split thickness skin allograft for venous leg ulcers

Robert S Kirsner [1], David Margolis [2], Arti Masturzo [3], Katie Bakewell [4]

Affiliations + expand

PMID: 32428972 DOI: 10.1111/wrr.12818

862 ulcers in 742 patients were selected from a large wound EMR database and analyzed. All patients received standard wound care prior to allograft application. Impact of ulcer duration, number of applications, ulcer size, and time to application were analyzed.

VLUs receiving allograft within 90 days of initial presentation are 1.4 times more likely to heal vs those receiving their first BSA application after 90 days of standard of care (95% CI: [1.05, 1.86], *P*=.02)

VLUs treated earlier had better healing outcomes. Clinicians may consider more aggressive and timely treatment for refractory VLUs.

Native ECM Scaffold Transitioning to BLCC Supported Healing of a Venous Leg Ulcer

5 applications of BLCC

- 51y Female with rheumatoid arthritis
- History: Chronic ulcer for years
- Previous treatments: Debridement and surgical reconstruction
- Site of care
  - Inpatient hospital
  - Clinic
  - Outpatient management



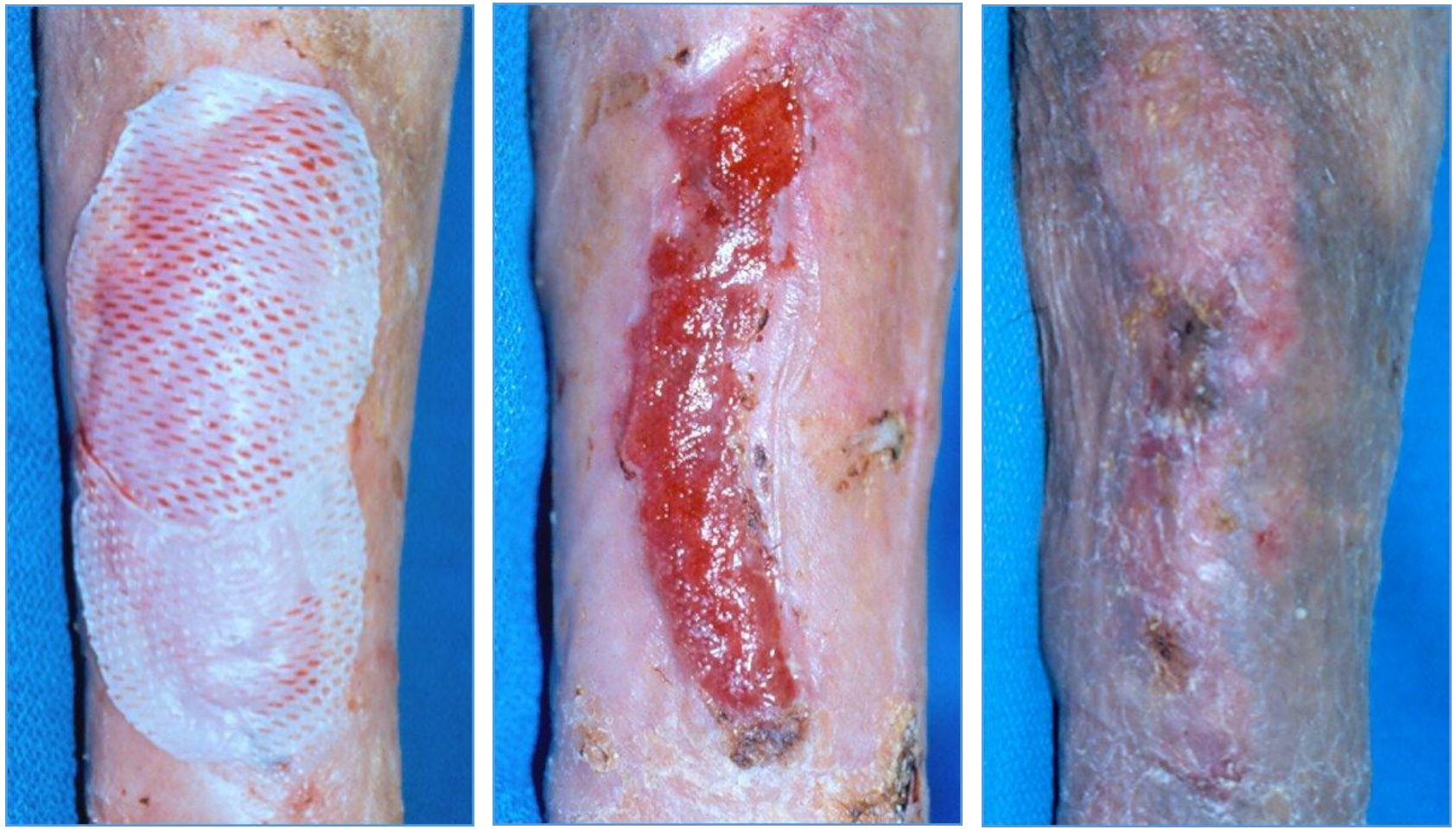




BLCC Stimulated Healing of a Venous Leg Ulcer

3 applications of BLCC to stimulate healing

- 76y Female with CVI, HTN, DM
- History: Chronic VLU for 9 months
- Previous treatments: Compression, trental and venous intervention



CVI = chronic venous insufficiency; HTN = hypertension; DM = diabetes mellitus.

Conclusion 1:
Chronic wounds are common and costly

Conclusion 2:
Baseline and longitudinal predictors can assist in identifying at-risk wounds

Conclusion 3:
Clinica Trial (Efficacy) and Real-World Data (Effectiveness) Both Provide Important Information To Drive Decision Making

Conclusion 4:
Advanced products speed healing of hard-to-heal wounds, but application is often delayed